REMARKS

Claim 10 has been amended by deleting the word "optionally." No new matter has been added. The Office Action has objected to claim 10 as being improper dependent form for failing to further limit the subject matter of a previous claim. In response, Applicants have amended claim 10, such that claim 10 further limits the scope of claim 5. Thus, Applicants contend that the objection is moot in view of amended claim 10 and respectfully request that it be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 102(e)

PEIRIS I

The Office Action maintains the rejection of claims 5-6, and 8-16 as being anticipated under 35 U.S.C. § 102(e) by U.S. patent No. 7,375,202 to Peiris *et al.* (hereinafter "Peiris I"). In particular, the Office Action alleges that the amendmends made to claim 5 did not change the scope of claim 5. The Office Action alleges that step (iii) of claim 5 recites performing real-time PCR on the nucleic acid of the pathogenic infectious agent and Peiris I discloses said limitation. Moreover, the Office Action points to col. 33-34 of Peiris I to support the anticipation rejection, alleging that claim 5 as amended requires only the nucleic acid of the pathogenic infectious agent.

In response, Applicants respectfully disagree with the propriety of this anticipation rejection. First, Applicants point out that a patent claim is anticipated by prior art if a single prior art reference discloses every limitation of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed. Cir.1987). If a single claim limitation is missing from the reference, then the reference does not anticipate the claim. Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569 (Fed.Cir.1984).

Applicants respectfully submit that Peiris I does not disclose a method that recites the sequential steps, as recited in claim 5, of isolating a nucleic acid of pathogenic infectious agent,

amplifying the nucleic acid of the pathogenic infectious agent, and thereafter performing Real Time PCR on the nucleic acid of the pathogenic agent.

The portions of Peiris I pointed out by the Office Action (namely, columns 33-34, section 6.7) disclose multiple independent experiments or procedures. Specifically, column 33 discloses a distinct and independent procedure consisting of a step of RT-PCR performed directly on the clinical specimen (*see* lines 16-51 and specifically lines 34-36), or a different procedure, beginning with culturing of the virus from two patients followed by a RT-PCR step (*see* lines 54-58). There is no teaching here of the step of RT-PCR being preceded by a pre-amplification step, as recited in pending claim 5.

Further in contrary to the assertion of the Office Action, column 34 discloses yet another distinct and independent procedure, which includes RNA extraction, reverse transcription, followed by PCR (*see* lines 1-46). Here, there is no teaching of RT-PCR, nor any pre-amplification step before RT-PCR. Column 34 also discloses yet another procedure, which includes an extraction step (*see* line 50) followed by a reverse transcription step (see line 52). There is a DNA amplification step (*see* line 56) followed by a PCR step (*see* line 62). However, in contrast to the present invention, there is no teaching of a pre-amplification step before the RT-PCR step. In other words, the amplification of Peiris is the polynucleotide-amplifying nature of Peiris's real-time PCR step and not a further independent pre-amplification step prior to real-time PCR step, as taught and claimed in the present invention.

The present invention is directed to a method for detection of nucleic acid of a pathogenic infectious agent comprising the sequential steps of (a) isolating the nucleic acid of the pathogenic infectious agent, (b) amplifying the nucleic acid of the pathogenic infectious agent, and (c) performing Real Time PCR on the nucleic acid of the pathogenic infectious agent. Applicants respectfully highlight that if a single claim limitation is missing from the reference, then the reference does not anticipate the claim.

It is acknowledged that amplification by itself is not new and RT-PCR by itself also is not new. However, the claimed invention is not directed to these isolated steps. None of the approaches of Peiris I teach or suggest the method recited in claim 5, which provides, after

isolation of a nucleic acid, an amplifying step which is then followed by a Real Time PCR step. Applicants respectfully highlight that the present invention provides that the use of a pre-amplification step prior to RT-PCR provides a surprising range of benefits including greater detection levels, improved sensitivity and quicker times than provided by conventional PCR techniques alone (*see* for example paragraph [0076] of the published application). It would be improper to pick different steps from distinct procedures in Peiris I and assert that they are used together and therefore anticipate pending claims 5-6, 8-16.

For at least the foregoing reasons, Applicants respectfully contend that claim 5 is not anticipated by Peiris I. With respect to dependent claims 6, and 8-16, applicants respectfully submit that they are all not anticipated by virtue of their dependency from independent claim 5. In view of the above, withdrawal of the rejection of claims 5-6 and 8-16 under 35 U.S.C. §102(e) as being anticipated by Peiris I is respectfully requested.

PEIRIS II

Claims 5-16 have also been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. patent No. 7,267,942 to Peiris *et al.* (hereinafter "Peiris II"). The Office Action alleges that the claims as amended do not require PCR product of the first amplification for subsequent real-time PCR and for the same reasons as outlined for Peiris I, the Office Action alleges Peiris II anticipates the instant claims.

In response, for at least the same reasons as outlined *supra* for refuting Peiris I as an anticipatory reference, Applicants incorporate herein and repeat said position regarding Peiris II. Here, independent claim 5 is a method claim with active steps, and as such Applicants respectfully disagree with the rejection that is based on the assertion that the claims do not require the product of the amplification step for subsequent real-time PCR. Specifically, the present invention is directed to a method for detection of nucleic acid of a pathogenic infectious agent comprising the sequential steps of (a) isolating the nucleic acid of the pathogenic infectious agent, (b) amplifying the nucleic acid of the pathogenic infectious agent, and (c) performing Real Time PCR on the nucleic acid of the pathogenic infectious agent.

Applicants respectfully submit that Peiris II does not teach a method for detection of nucleic acid of a pathogenic infectious that comprises the sequential steps of amplifying the nucleic acid of a pathogenic infectious agent followed by performing Real Time PCR on the nucleic acid of the pathogenic infectious agent. The section in Peiris II that was previously cited (column 11, lines 16-47) discloses the use of real-time quantitative PCR to detect the presence of hSARS virus. The amplification disclosed therein refers to the amplification that is part of the real-time PCR. Claim 5 refers to a pre-amplification step, separate from the real-time PCR step. As noted *supra*, neither Peiris I or Peiris II teach or suggest such a separate pre-amplification step, and that the use of a pre-amplification step prior to RT-PCR provides a surprising range of benefits (*see*, for example, paragraph [0076] of the published application).

For at least the foregoing reasons, Applicants respectfully contend that claim 5 is not anticipated by Peiris II. With respect to dependent claims 6-16, applicants respectfully submit that they are all not anticipated by virtue of their dependency from independent claim 5. In view of the above, withdrawal of the rejection of claims 5-16 under 35 U.S.C. §102(e) as being anticipated by Peiris II is respectfully requested.

There being no other outstanding issues, it is believed that the application is in condition for allowance, and such action is respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

The undersigned hereby authorizes the Commissioner to charge any fee insufficiency and credit any overpayment associated with this submission to Deposit Account No. 08-1935.

Respectfully submitted,

/Shahrokh Falati/

Date: February 24, 2010

Shahrokh Falati, Ph.D.
Attorney for Applicants
Registration No. 58,160

Please address correspondence to:
Heslin Rothenberg Farley & Mesiti P.C.
5 Columbia Circle
Albany, NY 12203
Tel.: 518-452-5600;
Fax: 518-452-5579
Customer No.: 23,405